

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. 98F-0484]

Indirect Food Additives: Polymers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

DMB

Display Date	8/20/00
Publication Date	8/31/00
Certifier	[Signature]

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of di-2-ethylhexyl terephthalate as a component of closures with sealing gaskets for food containers. This action responds to a petition filed by Eastman Chemical Co.

DATES: This rule is effective *[insert date of publication in the Federal Register]*. Submit written objections and request for a hearing by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3086.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of July 2, 1998 (63 FR 36246), FDA announced that a food additive petition (FAP 8B4593) had been filed by Eastman Chemical Co., P.O. Box 431, Kingsport, TN 37662. The petition proposed to amend the food additive regulations in § 177.1210 *Closures with sealing gaskets for food containers* (21 CFR

177.1210) to provide for the safe use of di-2-ethylhexyl terephthalate as a component of closure-sealing gaskets for food containers.

FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and therefore, that the regulations in § 177.1210 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 8B4593. No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by [*insert date 30 days after date of publication in the Federal Register*]. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific

factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 177

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 177 is amended as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for 21 CFR part 177 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 177.1210 is amended in the table in paragraph (b)(5) by alphabetically adding an entry under the headings “List of substances” and “Limitations” to read as follows:

§ 177.1210 Closures with sealing gaskets for food containers.

* * * * *

List of substances	Limitations (expressed as percent by weight of closure-sealing gasket composition)
Di-2-ethylhexyl terephthalate (CAS Reg. No. 006422-86-2).	For use as a plasticizer at levels not exceeding 75 parts per hundred by weight of permitted vinyl chloride homo- and/or copolymer resins used in contact with food of Types I, II, IV-B, VI-A, VI-B, VI-C (up to 15 percent alcohol by volume), VII-B, and VIII described in § 176.170(c) of this chapter, table 1, and under conditions of use A through H described in § 176.170(c) of this chapter, table 2.

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Dated: 8/21/00
August 21, 2000

L. Robert Lake
L. Robert Lake,
Director of Regulations and Policy,
Center for Food Safety and Applied Nutrition.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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J. Windsor